K072581

510(K) SUMMARY

JAN - 8 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is: _____.

Submitter:

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Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
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- **Contact Person:**

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Nanshan, Shenzhen, 518057, P. R. China

- **Date Prepared:**

Sep. 5, 2007

Name of the device:

- **Trade/Proprietary Name:** PM-60 Pulse Oximeter
- **Common Name:** Pulse Oximeter
- **Classification**

21 CFR 870.2700 Oximeter	Class II
21 CFR 870.2710 Oximeter, Ear	Class II

Legally Marketed Predicate Devices:

K070791 PM-8000 Express Patient Monitor, Shenzhen Mindray Bio-Medical

Electronics Co., Ltd

K051352 OxiMax NPB-40 Pulse Oximeter, Nellcor Puritan Bennett.

Description:

The PM-60 Pulse Oximeter is a handheld device that measures parameters of functional pulse oxygen saturation (SpO_2) and pulse rate (PR). It suits for adult, pediatric and neonatal patients.

The SpO_2 measurement of PM-60 is based on the absorption of pulse blood oxygen to red and infrared light by means of sensor and SpO_2 measuring unit. The light-electronic transducer in sensor converts the pulse red and infrared light modulated by pulse blood oxygen into electrical signal, the signal is processed by hardware and software of the unit. The pleth curve and numeral value of SpO_2 will be obtained.

PM-60 can be used in spot-check mode and continuous monitoring mode, which is selectable. It can be powered by alkaline batteries or Li-ion battery, and the latter is rechargeable with a charger stand. Through a color TFT display, users can view the data and operate the device. The audible and visual alarms are also adjustable.

During SpO_2 measuring, operators can export the data in real-time through the infrared port, and export trend data through the multi-functional connector. After exporting, operators can review and printing the data with the PC data management system (PMS) software.

Statement of intended Use:

The PM-60 handheld Pulse Oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (SpO_2) and pulse rate (PR) of single adult, pediatric and neonatal patients in hospitals, out-of-hospital transport and home care.

Testing:

Laboratory testing was conducted to validate and verify that the PM-60 Pulse Oximeter met all design specifications, including EMC, electrical, mechanical durability, safety, temperature/humidity, and etc. Results of these tests demonstrate compliance to the requirements of all applied standards.

Conclusion:

PM-60 Pulse Oximeter has been demonstrated that it is substantially equivalent to the predicate devices. Testing results demonstrate that there are no new questions of safety and effectiveness when compared to the legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2008

Shenzhen Mindray Bio-Medical Electronics Company, Limited
C/O Ms. Susan D. Goldstein-Falk
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K072581
Trade/Device Name: PM-60 Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: November 29, 2007
Received: December 27, 2007

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

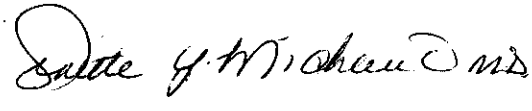
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit #E

510(k) Number (if known): _____

Device Name: PM-60 Pulse Oximeter

Indications For Use:

The PM-60 handheld Pulse Oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (SpO_2) and pulse rate (PR) of single adult, pediatric and neonatal patients in hospitals, out-of-hospital transport and home care.

Prescription Use __X___ **OR** **Over-The Counter Use _____**
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

0024

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